MAR 1 3 2013

SECTION 5 – 510(k) Summary
Modified Capiox® RX Oxygenator/Reservoir

Submitter Information:

Contact:

This submission was prepared in February 2013 by:

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This submission was prepared for:

Terumo Cardiovascular Systems Corporation
125 Blue Ball Road
Elkton, MD 21921
Registration #1124841

Device Names/Classifications:

Proprietary Name	Classification Name	Common Name
Capiox® RX Hollow Fiber Oxygenator with/without Hardshell Reservoir	Cardiopulmonary Bypass Oxygenator (Code: DTZ)	Blood Gas Oxygenator
	Cardiopulmonary Bypass Blood Reservoir (Code DTN)	Blood Reservoir

Predicate Device:

The device submitted in this 510(k) maintains characteristics that are substantially equivalent in intended use, design, technology/principles of operation, materials and specifications to the following devices:

CAPIOX® RX Hollow Fiber Oxygenator with/without Hardshell Reservoir (K062381)

Intended Use:

The intended use remains the same as the intended use in the cleared submission (K062381). There have been no changes to the indications or intended use of the modified devices.

The (modified) CAPIOX® RX Hollow Fiber Oxygenator with/without Hardshell Reservoir Intended Use:

The CAPIOX® RX Hollow Fiber Oxygenators with/without Hardshell Reservoir are intended to be used to exchange gases between blood and a gaseous environment to satisfy the gas exchange needs of a patient during cardiopulmonary bypass surgery.
The integral heat exchanger is used to warm or cool blood and/or perfusion fluid as it flows through the device.
The (detachable) hardshell reservoir(s) is (are) used to store blood during extra-corporeal circulation from both venous line and the cardiotomy line (via gravity or vacuum assisted venous drainage procedures). The reservoir contains a venous section that is comprised of a filter and defoamer to facilitate air bubble removal. The cardiotomy section of the reservoir contains a filter to remove particulate matter and a defoamer to facilitate air bubble removal. The reservoir may also be used for Post Operative Chest Drainage Procedures.
The CAPIOX® RX Oxygenators with/without Hardshell Reservoirs can be used in procedures lasting up to 6 hours.
The CAPIOX® RX15 is for use with patients when the required blood flow rate will not exceed 5.0 L/min when used with a 4 Liter Reservoir; and when the required blood flow rate will not exceed 4.0 L/min when used with a 3 Liter Reservoir).
The CAPIOX® RX25 is for use with patients when the required blood flow rate will not exceed 7.0 L/min.

Principles of Operation and Technology:

The technological characteristics and principles of operation remain the same as that of the predicate device (K062381). There have been no changes to the fundamental scientific technology of the modified devices.

The modified and predicate Capiox RX Oxygenator utilize a porous fiber technology to facilitate the transfer of gases between a blood-phase environment and a gas-phase environment for the intent of satisfying the gas exchange needs of a patient during cardiopulmonary bypass surgery. A wound fiber bundle offers the porous membrane surface to sufficiently permit the movement of gases through the walls of the hollow fibers via diffusion.

The modified and predicate Capiox RX device have an integrated heat exchanger that is comprised of stainless steel encased in a polycarbonate housing. The stainless steel acts as a heat transfer material that permits heat that is generated from a temperature controlled external water bath to transverse across the walls of the stainless steel to effect the necessary temperature change upon circulating blood.

With respect to the filtration of blood, the modified Capiox RX Reservoir relies upon mechanical entrapment of particulates and emboli within the filter mesh as a means to remove those particulates from the blood.

Design and Materials:
With respect to the design of the oxygenator, the design of the modified Capiox RX oxygenator device is unaffected by the changes being incorporated at this time. The subject of this Special 510(k) is a modification being made to the Hardshell Reservoir.

With respect to the design of the Hardshell Reservoir, the reservoir component remains identical to the design of the original reservoir that was cleared by FDA with (K062381) – except that a positive pressure relief valve will be included on the lid of the reservoir. The intent of the relief valve is to eliminate excessive pressure that *could* accumulate in a reservoir during bypass procedures.

The materials that are used in the construction of the Capiox RX Hollow Fiber Oxygenator may include, but are not limited to, nylon, polycarbonate, stainless steel, polyvinyl chloride, polyurethane, polyester, polypropylene, polyethylene and X-Coating™.

Terumo Cardiovascular Systems concludes that the differences between the modified device and the predicate device do not affect the intended use of the device nor do they affect safety and effectiveness of the device when used as labeled.

Performance Evaluations:
Clinical studies involving patients are not necessary to demonstrate substantial equivalence of the subject device to the predicate device. Terumo Cardiovascular Systems conducted the following *in-vitro* performance evaluations to demonstrate the functional equivalence of the subject device to the predicate device.

Substantial equivalence is demonstrated with the following *in-vitro* performance evaluations:

- Assessment of Reservoir Pressure during Simulated Bypass Procedures
- Positive and Negative Pressure Testing of the Reservoir
- Pressure Relief Valve performance following application of vacuum to the reservoir
- Pressure Relief Valve-to-Reservoir Interface Testing
- Usability Testing
- Sterilization Assessment
- Shock Drop and Vibration Testing
- Artificial Conditioning to Shelf-Life of the product

Substantial Equivalence Comparison:
In demonstrating substantial equivalence of the *modified* CAPIOX® RX Hollow Fiber Oxygenator with/without Hardshell Reservoir to the predicate CAPIOX® RX Hollow Fiber Oxygenator with/without Hardshell Reservoir, a comparative study and/or assessment was performed in each of the following areas:

- Intended use
- Target Population
- Duration of use
- Product labeling
- Product design
- Materials
- Principles of Operation and Technology
- Device Performance

Substantial Equivalence Statement:
The *modified* CAPIOX® RX Hollow Fiber Oxygenator with/without Hardshell Reservoir is substantially equivalent in intended use, target population, duration of use, labeling, design, materials, principles of operation and technology, and performance to the predicate CAPIOX® RX Hollow Fiber Oxygenator with/without Hardshell Reservoir. Any noted differences between the subject device and the predicate devices do not raise new issues of safety and effectiveness.

Conclusion:
Based upon the comparative studies and analyses, Terumo Cardiovascular Systems concludes that the *modified* CAPIOX® RX Hollow Fiber Oxygenator with/without Hardshell Reservoir is *substantially equivalent* to the predicate *modified* CAPIOX® RX Hollow Fiber Oxygenator with/without Hardshell Reservoir. It is further concluded that any recognized differences noted during the assessments do not raise new issues of patient/user safety or product effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

March 13, 2013

Terumo Cardiovascular Systems Corporation
c/o Suzanne Grenier
125 Blue Ball Road
Elkton, MD 21921

Re: K130333
Trade/Device Name: CAPIOX RX Hollow Fiber Oxygenators with/without Hardshell Reservoirs
Regulation Number: 21 CFR 870.4350
Regulation Name: Cardiopulmonary Bypass Oxygenator
Regulatory Class: Class II
Product Code: DTZ
Dated: February 8, 2013
Received: February 14, 2013

Dear Ms. Grenier:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Matthew G. Hillebrenner

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SECTION 4 – Indications for Use
Modified Capiox RX Oxygenators/Reservoirs

K130333

510(k) Number (if known): Unknown at time of Submission

Device Name: **CAPIOX® RX Hollow Fiber Oxygenator with/without Hardshell Reservoir**

Indications For Use:

Indications for Use as presented in the Instructions for Use:

The CAPIOX RX is intended to be used during open heart surgical procedures requiring cardiopulmonary bypass for periods up to 6 hours.
The CAPIOX RX25 is used with patients when required blood flow rate will not exceed 7 L/min. The CAPIOX RX15 is for use with patients when required blood flow rate will not exceed 5 L/min (4L/min if using product codes CX*RX15RW30 or CX*RX15RE30). The CAPIOX RX Hardshell Reservoir is also intended for use in vacuum assisted venous drainage procedure, in post-operative chest drainage and autotransfusion procedures to aseptically return the blood to the patient for blood volume replacement.

Indications for Use as described in the 510(k):

The CAPIOX® RX Hollow Fiber Oxygenators with/without Hardshell Reservoir are intended to be used to exchange gases between blood and a gaseous environment to satisfy the gas exchange needs of a patient during cardiopulmonary bypass surgery.
The integral heat exchanger is used to warm or cool blood and/or perfusion fluid as it flows through the device.
The (detachable) hardshell reservoir(s) is (are) used to store blood during extra-corporeal circulation from both venous line and the cardiotomy line (via gravity or vacuum assisted venous drainage procedures). The reservoir contains a venous section that is comprised of a filter and defoamer to facilitate air bubble removal. The cardiotomy section of the reservoir contains a filter to remove particulate matter and a defoamer to facilitate air bubble removal. The reservoir may also be used for Post Operative Chest Drainage Procedures.
The CAPIOX® RX Oxygenators with/without Hardshell Reservoirs can be used in procedures lasting up to 6 hours.
The CAPIOX® RX15 is for use with patients when the required blood flow rate will not exceed 5.0 L/min when used with a 4 Liter Reservoir; and when the required blood flow rate will not exceed 4.0 L/min when used with a 3 Liter Reservoir).
The CAPIOX® RX25 is for use with patients when the required blood flow rate will not exceed 7.0 L/min.

Prescription Use ___XX___ OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (Part 21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Matthew G. Hillebrenner